**U.S. ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR PART 503**

**[FRL - ]**

# STANDARDS FOR THE USE OR DISPOSAL OF SEWAGE SLUDGE

**AGENCY:** Environmental Protection Agency

**ACTION:** Proposed Rule

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to amend management standards for sewage sludge by adding a numeric concentration limit for dioxin and dioxin-like compounds ("dioxins") in sewage sludge that is applied to the land, and monitoring, record keeping and reporting requirements for dioxins in sewage sludge that is land applied. Today's action also presents the results of risk assessments for dioxins in sewage sludge that is applied to the land, placed in surface disposal units, or incinerated. Based on these risk assessments, the Agency is not proposing additional numeric standards or management practice requirements for dioxins in sewage sludge that is placed in surface disposal units or incinerated.

EPA is proposing a standard for dioxins in sewage sludge that is applied to the land in order to protect public health and the environment from unreasonable risks of exposure to dioxins. The Agency's risk assessment for land application of sewage sludge estimates that sewage sludge with concentrations of dioxins above the proposed limit may present an unreasonable cancer risk to specific highly exposed individuals. The purpose of this standard would be to prohibit land application of

sewage sludge containing concentrations of dioxins above the limit, and thereby protect the health of highly exposed individuals as well as the health of the general population.

We are also proposing to exclude from the proposed numeric limit and monitoring requirements treatment works with a flow rate equal to or less than one million gallons per day and certain sludge-only entities that receive sewage sludge for further processing prior to land application. This exclusion is based on the relatively small amount of sewage sludge that is prepared by these facilities and entities and, therefore, the low probability that land application of these materials could significantly increase risk from dioxins to human health or the environment.

Finally, we are proposing technical amendments to the frequency of monitoring requirements. These amendments are intended to clarify but, with one exception, not alter the monitoring schedule in the existing sludge rule. The one exception would require preparers of material derived from sewage sludge to determine the appropriate monitoring schedule based on quantity of material derived rather than quantity of sewage sludge received for processing.

**DATES:** Comments must be received or postmarked on or before midnight [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]

**ADDRESSES:** Written comments and enclosures should be mailed or hand-delivered to: Part 503 Sewage Sludge Use or Disposal Rule; Docket Number W-99-18, Comment Clerk, Water Docket MC-4101, Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460. Comments may also be submitted electronically to OW-Docket@epamail.epa.gov. For additional information see **Additional Docket Information** section below.

**FOR FURTHER INFORMATION CONTACT:**

Arleen Plunkett, U.S. Environmental Protection Agency, Office of Water, Health and Ecological Criteria Division (4304), 401 M Street, SW, Washington, DC 20460. (202) 260-3418.

**SUPPLEMENTARY INFORMATION:**

## I. Regulated Entities

Entities potentially regulated by this proposed action are those that prepare sewage sludge and/or use or dispose of the sewage sludge through application to the land. Regulated categories and entities include:

| Category | Examples of Regulated Entities |
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| State/Local/Tribal Government | Publicly owned treatment works and other treatment works that treat domestic sewage, that prepare sewage sludge and/or apply sewage sludge to the land |
| Federal Government | Federal Agencies with treatment works that treat domestic sewage, that prepare sewage sludge and/or apply sewage sludge to the land |
| Industry | Privately-owned treatment works that treat domestic sewage, and persons who receive sewage sludge and change the quality of the sewage sludge before it is used or disposed |

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your facility or company is regulated by this action, you should carefully examine the applicability criteria in §§ 503.1 and 503.10 of title 40 of the Code of Federal Regulations. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding "**FOR FURTHER INFORMATION CONTACT**" section.

## II. Additional Docket Information

The record for this rulemaking has been established under docket number W-99-18 and includes supporting documentation as well as the printed paper versions of electronic materials. When submitting written comments to the Water Docket, (see **ADDRESSES** section above) please reference docket number W-99-18 and submit an original and three copies of your comments and enclosures (including references). For an acknowledgment that we have received your information, please include a self-addressed, stamped envelope. EPA will not accept facsimiles (faxes). Comments may also be submitted electronically to: ow-docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII, WP5.1, WP6.1or WP8 file avoiding the use of special characters and form of encryption. Electronic comments must be identified by docket number W-99-18. Comments and data will also be accepted on discs in WP5.1, WP6.1, WP8, or ASCII file format. To ensure that EPA can read, understand, and, therefore, properly respond to comments, the Agency would prefer that commenters cite, where possible, the paragraph(s) or sections in the notice or supporting documents to which each comment refers. Commentors should use a separate paragraph for each issue.

The record is available for inspection from 9:00am to 4:00pm Eastern Standard or Daylight time, Monday through Friday, excluding legal holidays at the Water Docket, EB 57, USEPA Headquarters, 401 M Street, SW, Washington, D.C. 20460. For access to the docket materials, please call 202-260-3027 to schedule an appointment.

For information on the existing rule in 40 CFR Part 503, you may obtain a copy of *A Plain English Guide to the EPA Part 503 Biosolids Rule* on the Internet at http://www.epa.gov/owm/bio.htm or request the document (EPA publication number EPA/832/R-

93/003) from: Municipal Technology Branch, Office of Wastewater Management (4204), Office of Water, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, D.C. 20460.

## III. Legal Background

### A. Legal Authority Under Which EPA is Proposing to take Action

EPA is proposing regulatory amendments to 40 CFR part 503 under section 405(d) and (e) of the Clean Water Act (CWA), 33 U.S.C. §1345(d), (e). In 1987, Congress amended section 405 and, for the first time, set forth a comprehensive program for reducing the potential environmental risks and maximizing the beneficial use of sewage sludge. As amended, section 405(d) of the CWA requires us to establish numeric limits and management practices that protect pubic health and the environment from the reasonably anticipated adverse effects of toxic pollutants in sewage sludge. Section 405(e) prohibits any person from disposing of sewage sludge from a publicly owned treatment works (POTW) or other treatment works treating domestic sewage through any use or disposal practice for which regulations have been established pursuant to section 405 except in compliance with the section 405 regulations.

Amended section 405(d) also established a timetable for the development of the sewage sludge use or disposal regulations. H.Rep. No. 1004, 99th Cong. 2d. Sess. 158 (1986). Section 405(d) calls for two rounds of sewage sludge regulations. The first round required EPA to establish numeric limits and management practices for toxic pollutants we identified which, based on "available information on their toxicity, persistence, concentration, mobility, or potential for exposure may be present in sewage sludge in concentrations which may adversely affect public health or the environment." CWA

§405(d)(2)(A). The second round concerns toxic pollutants not regulated in the first round "which may adversely affect public health or the environment." CWA §405(d)(2)(B).

EPA did not meet the timetable in section 405(d) for promulgating the first round of regulations, and a citizen's suit was filed to require EPA to fulfill this mandate. (*Gearhart v. Browner,* Civ. No. 89-6266-HO (D. Ore.)). In accordance with the consent decree entered by the court in this case, EPA promulgated the first round of sewage sludge regulations, 40 CFR Part 503. 58 FR 9248 (Feb. 19, 1993) ("Round One"). The consent decree also established a schedule for identifying additional toxic pollutants in sewage sludge and completing the second round of regulation under section 405(d)(2)(B) ("Round Two"). First, in May 1993, EPA identified 31 pollutants not regulated in Round One that we were considering for regulation. In November 1995, EPA notified the court that it was revising the original list of 31 pollutants and considering two pollutant groups for the second round: polychlorinated dibenzo-p-dioxins/dibenzofurans (PCDD/F) and dioxin-like coplanar polychlorinated biphenyls (PCBs). Under the consent decree as modified by court order signed January 5, 1994, the Administrator is required to sign a notice for publication proposing such regulations no later than December 15, 1999, and to sign a notice taking final action on the proposal no later than December 15, 2001.

### B. Prior Regulation of Sewage Sludge Use or Disposal Under the Clean Water Act

As noted above, CWA § 405(d)(2)(A) required the first round of regulation to be based on "available information on [the] toxicity, persistence, concentration, mobility, or potential for exposure" of toxic pollutants in sewage sludge. After extensive consultation, EPA initially selected a list of some

50 pollutants to analyze. We then collected available data on those pollutants and developed further information on their toxicity, persistence, means of transport, and environmental fate. For 40 pollutants, we also developed preliminary information on the relative frequency of concentration by analyzing their concentrations in the sewage sludge of 43 to 45 POTWs in 40 cities, which we presented in the report *Fate of Priority Pollutants in Publicly Owned Treatment Works* (the "40 Cities Study"). Based on this information and a screening assessment to determine whether any or all of the pollutants may adversely affect human health or the environment, we sorted the pollutants into three groups: (1) those which did not exceed a human health or environmental criterion at the highest concentrations shown in the 40 Cities Study; (2) those for which we lacked sufficient data, and (3) those which warranted further risk analysis for possible regulation under section 405(d)(2)(A) (58 FR 9263-9265).

For the final Round One regulation, we conducted a National Sewage Sludge Survey (NSSS) (Notice of Data Availability, 55 FR 47210 (Nov. 9, 1990)) (USEPA, 1990). We gathered data from sewage sludge samples taken at 180 POTWs, as well as survey data from 475 public treatment facilities with at least secondary wastewater treatment. We designed the NSSS to produce national estimates of (1) concentrations of toxic pollutants in municipal sewage sludge, (2) sewage sludge generation and treatment processes, (3) sewage sludge use or disposal practices and alternative use or disposal practices, and (4) sewage sludge treatment and disposal costs. We analyzed the samples of sewage sludge for a total of 412 pollutants, including every organic, pesticide, dibenzofuran, dioxin and PCB analyte for which EPA had gas chromatography and mass spectrometry (GC/MS) standards (58 FR 9268-9269).

EPA published the Round One standards (40 CFR part 503) on February 19, 1993. These regulations established requirements for the final use or disposal of sewage sludge under three circumstances:

- when it is applied to the land for a beneficial purpose, including use in home gardens;
- when it is placed in a surface disposal site, including sewage sludge-only landfills; and
- when it is incinerated.

For land application, Part 503 set numeric limits for nine heavy metals in sewage sludge; established operational standards to reduce or eliminate pathogens in sewage sludge and to reduce vector attraction; and established management practices to restrict the application rate and placement of sewage sludge on the land. Regarding surface disposal, part 503 set numeric limits for three metals in sewage sludge, established requirements for the placement and management of a surface disposal site, and established operational standards to reduce or eliminate pathogens in sewage sludge and to reduce vector attraction. For incineration in a sewage sludge incinerator (SSI), part 503 established limits for five pollutants in the sewage sludge fed to a SSI and adopted standards under the Clean Air Act for two additional pollutants. We also established performance standards for SSIs through an operational standard for total hydrocarbon or carbon monoxide emissions. Part 503 also allows disposal of sewage sludge in a municipal solid waste landfill in accordance with 40 CFR part 258. The final rule also requires some monitoring, record keeping and reporting. Standards apply to publicly- and privately-owned treatment works that generate or treat domestic sewage sludge and to anyone who uses or disposes of sewage sludge.

EPA has amended part 503 several times since its initial publication in February 1993. Following promulgation of the Round One rule, several petitions for review were filed challenging various aspects of the rule. In one petition, several mining and chemical concerns challenged the land application molybdenum limits. EPA amended Part 503 to delete the cumulative loading rate and pollutant concentration rate for molybdenum in sewage sludge to be land applied (59 FR 9095, Feb. 25, 1994). Also in that Federal Register notice, EPA added continuous monitoring of carbon monoxide as an alternative to continuous monitoring of total hydrocarbons in the sewage sludge incinerator requirements. In another case, *Leather Industries of America v. EPA*, 40 F.3d 392 (D.C. Cir. 1994), the court remanded several of the land application requirements. As a result of that decision, EPA deleted all numerical standards for chromium in sewage sludge to be land applied and adjusted the Table 3 limit for selenium. (60 FR 54764, Oct. 25, 1995). EPA is considering further amendments to address the issues remaining from the partial remand as well as other issues. EPA most recently amended part 503 to make a number of technical amendments, provide some regulatory flexibility, and make the sewage sludge incinerator standards self-implementing. (64 FR 42552, Aug. 4, 1999).

For a detailed discussion of the Part 503 Rule, see *A Plain English Guide to the EPA Part 503 Biosolids Rule,* which is available as stated in the ADDRESSES section of this preamble.

## IV. Proposed Round Two Sewage Sludge Regulation

### A. Selection of Dioxins for Round Two

Chlorinated dioxins are unintentional byproducts of certain manufacturing processes and incomplete combustion of organic waste. Dioxins are not created in the sewage treatment process;

rather, treatment works concentrate those dioxins that enter the sewage treatment system from other sources. Dioxins present in the influent to a wastewater treatment works are partially concentrated in sewage sludge and partially discharged in the effluent. The few sewage treatment works that incinerate sewage sludge may generate small amounts of dioxins and coplanar PCBs during the process of combustion. Dioxins are biologically active organic compounds that cause a variety of health impacts on mammalian species, including humans, at very low and chronic doses. They are found in extremely small quantities in air, water and soil; however, they are persistent in the environment and bioaccumulate in the foodchain. (USEPA, 1994)

As described in Section III.B above, when EPA undertook the 40 Cities Study, we identified one group of pollutants, for which we lacked sufficient data. That group included polychlorinated dibenzo-p-dioxins and polychlorinated dibenzofurans.

In the subsequent National Sewage Sludge Survey (NSSS) (EPA 1990), we obtained additional data, which we used to perform an initial statistical screening of 412 additional toxic pollutants detected in sewage sludge. We then reviewed the scientific literature for toxicity, fate, effect, and transport information for the pollutants identified in the initial screening. We decided what pollutants to consider for possible regulation by comparing the calculated levels associated with adverse effects to the actual level and occurrence data from the NSSS.

The screening yielded a list of 31 pollutants or pollutant groups to be considered for the future regulation. We then conducted a Comprehensive Hazard Identification Study (USEPA, 1996), a screening type analysis that included dose-response evaluation, exposure assessment, and risk characterization. Our goal for the study was to identify pollutants that, based on very conservative or

worst case assumptions, might pose human health risks for a hypothetical individual with the greatest possible exposure through any of ten pathways. Based on this evaluation, we considered further assessment and possible regulation for dioxins/dibenzofurans and coplanar PCBs only.

### B. Proposed Requirements for Sewage Sludge that is Land Applied

#### 1. Overview of Proposed Requirements

Today's action proposes to amend 40 CFR 503.8, 503.9, 503.10, 503.13, and 503.16 to prohibit land application of sewage sludge that contains greater than 300 parts per trillion (ppt) toxic equivalents (TEQ) of dioxins. This proposed numeric standard would be expressed as 0.0003 milligrams TEQ per kilogram dry sewage sludge in § 503.13(b)(1) and (b)(3), Tables 1 and 3. See Section V.B. below, for an explanation of the risk assessment and how EPA determined that a limit of 300 ppt TEQ dioxins in sewage sludge that is land applied is protective of public health and the environment.

We are proposing to define "dioxins" to mean 29 specific congeners of polychlorinated dibenzo-p-dioxins, polychlorinated dibenzofurans, and coplanar PCBs. Today's proposed rule also requires monitoring, record keeping, and reporting to ensure that this numeric limit (300 ppt TEQ) is met. The proposal specifies two analytical methods that would be used to analyze sewage sludge to determine the level of dioxins/dibenzofurans and coplanar PCBs in sewage sludge. The Agency is proposing two alternative monitoring schedules based on the level of dioxins measured in sewage sludge. EPA is also proposing to exclude from compliance with the standards for dioxins and the monitoring requirement, treatment works that treat domestic sewage and that have a flow rate of one million gallons per day or less and certain small entities that derive material from sewage sludge received

from sewage treatment works ("sludge-only entities"). These proposed provisions are discussed in detail in the following sections.

### 2. Definition of Dioxins

The proposal includes a definition of "dioxins" to specify the seven 2,3,7,8,-substituted congeners of polychlorinated dibenzo-p-dioxins (PCDDs), the ten 2,3,7,8-substituted congeners of polychlorinated dibenzofurans (PCDFs), and the twelve coplanar PCB congeners to which the numeric standard applies. The vast majority of information on the toxicity of dioxins relates to the congener 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD). Animals exposed to 2,3,7,8-TCDD exhibit a variety of biological responses and adverse effects. These include both carcinogenic and non-carcinogenic effects. These effects are primarily classified as chronic effects and consequently they are generally associated with long term exposure over years and decades. Relatively speaking, these exposures and effects are observable at very low levels in the laboratory and in the environment when compared with other environmental toxicants (USEPA, 1994).

Studies to elucidate the mechanism of toxicity for 2,3,7,8-TCDD in mammalian species have indicated that the overall shape and chlorine substitution of this congener are keys to its biological potency. The fact that all of the lateral positions (the 2,3,7,8 positions) on the multi-ring system are substituted with chlorine and that the overall molecule assumes a flat or planar configuration apparently are essential factors that make this congener biologically active. Other congeners with a similar structure and chlorine substitution pattern are assumed to exhibit similar biological properties. These include the other six 2,3,7,8- chlorinated substituted dibenzo-p-dioxin congeners, the ten 2,3,7,8-chlorinated substituted dibenzofuran congeners and the 12 coplanar PCB congeners. Coplanar PCB

congeners are those congeners with no more than one ortho position and both para positions substituted with chlorine in the biphenyl ring system and the molecule assumes a relatively planar (i.e. flat) configuration.

The 300 ppt TEQ numeric limit would apply to these 29 congeners in ppt TEQ or nanograms TEQ per kilogram of dry sewage sludge. The TEQ concentration is calculated by multiplying the concentration of each congener in the sewage sludge by its corresponding "toxicity equivalent factor," or TEF, and then summing the resulting products from this calculation for all 29 congeners. The TEF schemes to be used are the International scheme described in USEPA, 1989, for the 17 2,3,7,8-substituted polychlorinated dibenzo-p-dioxins and polychlorinated dibenzofurans and the World Health Organization's TEF scheme (Van den Berg, 1998) for the 12 coplanar PCBs. We invite comment on the this proposed definition of dioxins.

### 3. Analytical Methods

EPA is proposing two methods for analyzing dioxins in sewage sludge to be land applied. One method, EPA Method No. 1613, Revision B (1613B) would be required for monitoring for the seven dioxin and ten dibenzofuran congeners. EPA Method No.1668 would be required for the 12 coplanar PCB congeners.

EPA proposes to use Method 1613, Revision B, *"Tetra-Through Octa-Chlorinated Dioxins and Furans by Isotope Dilution HRGC/HRMS."* Method 1613B is an approved test method (40 CFR part 136) for use in EPA's wastewater program for determining dioxins and furans. This test method is applicable to both aqueous and solid samples, but was fully validated through an

interlaboratory study prior to its promulgation only for use in wastewater. Method 1613B has not been approved in part 136 for sewage sludge (62 FR 48394, Sept. 15, 1997).

EPA proposes to use Method 1668, "Chlorinated Biphenyl Congeners in Water, Soil, Sediment, and Tissue by HRGC/HRMS." Method 1668 was developed by EPA to analyze coplaner PCBs in a variety of matrices, including sewage sludge. Method 1668 was validated in a single laboratory and tested in a second laboratory. These data were published in the draft method "Toxic Poly-Chlorinated Biphenyls by Isotope Dilution High Resolution Gas Chromatography/High Resolution Mass Spectrometry," EPA-821-R-97-001, March 1997. EPA revised the original version of this method to address additional PCB congeners. Method 1668A is the state-of-the-art test method for the measurement of PCB congeners, including coplanar PCBs; however it is still in draft. Method 1668A was validated in a single laboratory and peer reviewed by 21 laboratories, including EPA's laboratory in Bay St. Louis, Mississippi. Although Method 1668A has not gone through a full interlaboratory validation study yet, EPA has used this test method in monitoring surveys. Both Method 1668 and 1668A are in the docket for this rulemaking. If EPA finalizes Method 1668A before EPA takes final action on this proposed rulemaking, then the final rule would require use of Method 1668A. However, because Method 1668A is not final at this time, EPA is proposing the original version of Method 1668 to be used to analyze coplanar PCBs in sewage sludge.

EPA requests public comment on the use of these two test methods for compliance with monitoring requirements for sewage sludge. EPA also specifically requests comment on the use of Method 1668A for coplanar PCBs.

#### 4. Frequency of Monitoring Requirements

As stated above, EPA is proposing two alternative monitoring schedules based on the level of dioxins in sewage sludge to be land applied. According to existing information on the amounts of dioxins present in sewage sludge, levels can vary considerably from one source to another. However, we believe that the level of dioxins in sewage sludge, both nationally and from specific sources, is relatively constant over time and may possibly be decreasing (U.S. Conference of Mayors, 1999). This observation is derived from comparisons of dioxin concentrations found in the 1988 NSSS (USEPA, 1990) and the more recent Association of Metropolitan Sewerage Agencies (AMSA) survey (Green, et. al., 1995), together with anecdotal information from several locations.

We therefore believe it is appropriate to establish two monitoring schedules for dioxins in §503.16, depending upon the level of dioxins found in the initial two years of testing of the sewage sludge. Treatment works and other sewage sludge preparers (defined in §503.9(r)) that find the level of dioxin in their sewage sludge to be between 300 ppt TEQ and 30 ppt TEQ would be required to monitor annually. Treatment works and sludge preparers that measure dioxin levels of 30 ppt TEQ or less for two consecutive years would be required to monitor every five years thereafter.

We selected 30 ppt TEQ as the level to allow less frequent monitoring since it is a full order of magnitude less than the proposed numeric standard of 300 ppt TEQ (i.e., one-tenth). Given the observed trends described above, we believe it is unlikely that sewage sludge with 30 ppt TEQ or less will exceed the 300 ppt TEQ limit. This observation is consistent with: (1) our assumption that dioxins primarily enter sewage treatment facilities from diffuse background sources which inherently are less subject to short-term spikes in pollutant levels than point sources, and (2) a significant measured reduction in air emissions of dioxins, which are the principal contributors to these diffuse sources,

according the Agency's United States Dioxin Inventory (USEPA, 1998). Furthermore, any health risks associated with dioxin exposure from land application of sewage sludge would not be significantly affected over a short period of time such as five years, but rather would require long-term exposure at these levels to potentially present unreasonable health risks. For these reasons we believe a five-year monitoring frequency is appropriate for sewage sludge which was last measured at or below 30 ppt TEQ. We are specifically requesting comments and additional data on the validity of our assumptions concerning rates and degree of changes in levels of dioxins in sewage sludge and the reasonableness of the proposed monitoring schedule.

A treatment works or other person who prepares sewage sludge for land application would be able to switch to the reduced monitoring schedule if tests show that its sewage sludge contained 30 ppt TEQ or less in two consecutive annual tests. We believe that two consecutive annual tests are reasonable in order to ensure that the level of dioxins in the sewage sludge is consistently at or below the 30 ppt TEQ level. This is consistent with the existing provision in §503.16(a)(2), which allows the permitting authority to reduce the frequency of monitoring after sewage sludge has been monitored for two years. We are proposing these frequency of monitoring requirements for dioxins to be in a new paragraph (a)(3) in §503.16. We also specifically request comments on whether two consecutive years of monitoring results under 30 ppt TEQ should be required before allowing a reduced monitoring schedule.

We are also proposing to amend §503.16(a) to clarify, but not alter, existing frequency of monitoring requirements. We propose to separate the existing requirements contained in §503.16(a)(1) into two paragraphs, (a)(1) and (a)(2). Paragraph (a)(1) would contain the

requirements for monitoring concentrations of pollutants except dioxins, and paragraph (a)(2) would contain the requirements for monitoring compliance with pathogen reduction and vector attraction reduction requirements. Existing §503.16(a)(2) would be renumbered as §503.16(a)(4), but would be otherwise unchanged. These amendments are solely for the purpose of clarity and for expressing existing regulatory requirements in plain language, and they are not intended to reopen these requirements for comment. We invite comment on whether these proposed amendments unintentionally change the substance of the frequency of monitoring provisions currently in §503.16(a)(1).

Finally, we are proposing to amend footnote 1 to Table 1 in §503.16. Currently this footnote states that a person who prepares material derived from sewage sludge received from another preparer must determine the frequency of monitoring based on the quantity of sewage sludge received. Sewage sludge is often mixed with other materials to produce the material derived from sewage sludge that is ultimately applied to the land. We believe that the frequency of monitoring should be based on the quantity of product that is actually applied to the land. We therefore propose to amend the footnote to Table 1 to require the monitoring schedule to be based on the amount of sewage sludge or material derived from sewage sludge to be land applied.

**5. Small Preparer Exclusion**

We are proposing in today's action to exclude from the proposed requirements relating to dioxins, sewage treatment works with a wastewater flow of one million gallons per day (MGD) or less and sludge-only entities which prepare 290 dry metric tons or less of sewage sludge annually for land application. We estimate that a one MGD treatment works produces approximately 290 dry metric tons of sewage sludge annually. Sewage sludge from these small preparers would be excluded from the

limitation on dioxins in sewage sludge; thus these small preparers would not be required to monitor for dioxins. Such preparers could continue to land apply their sewage sludge with no further restriction due to the sludge's dioxin content. Septage pumpers and haulers would also not be required to comply with the limitation on dioxins and the associated monitoring requirements. (See 58 FR 9362 for a discussion of requirements applicable to septage haulers and under part 503.)

We believe that this exclusion is appropriate for several reasons. First, the vast majority of land-applied sewage sludge is produced by sewage treatment works with flow rates higher than one MGD. According to the 1988 NSSS, treatment works with flow rates of one MGD or less produce only 135,911 dry metric tons of sewage sludge annually for land application, or less than eight percent of the total sewage sludge that is land applied on an annual basis. Of the amount of land applied sewage sludge produced by those small treatment works, we estimate approximately 6800 dry metric tons (5%) contained in excess of the 254 ppt TEQ PCDD and PCDF. This estimate is based on PCDD and PCDF only since the NSSS did not measure coplanar PCBs. Our data indicates that sewage sludge containing 300 ppt TEQ dioxins typically would have 254 ppt TEQ PCDD and PCDF (USEPA, 1990; Green, et. al., 1995). Second, the probability that this small amount of sewage sludge (i.e., 42 dry metric tons per facility annually) could unreasonably increase health risks for any individual is extremely small. As further explained in Section V.B. of this preamble, the risk assessment assumes a much greater amount of sewage sludge is applied to the same piece of land over a long period of time. At this much higher application rate, the risk assessment estimates unacceptable increase in cancer risk only to "high-end" receptors. We have, therefore, concluded that the amounts of land-applied sewage sludge with dioxins in excess of 300 ppt TEQ produced by a treatment works with a

flow rate of one MGD or less or by small sludge-only entities does not pose an unreasonable risk. We request comment on our proposal to exclude small preparers from the limit for dioxins in sewage sludge to be land applied. We specifically invite comment on our proposal to exclude small entities which receive and further process sewage sludge prior to land application. We also specifically invite comment on how we propose to define such small entities.

We are, however, reserving the option of requiring initial monitoring and applying the limit for dioxins for small preparers (treatment works and sludge-only entities) which land apply sewage sludge. We are requesting information on the dioxin content and land application practices (e.g., annual application rates, numbers and sizes of sites and the number of applications per site) for sewage sludge from treatment works with a flow rate of one MGD or less. We specifically invite public comment on whether the Agency should promulgate such a requirement.

We are also proposing to exempt septage pumpers and haulers from the proposed limit for dioxins. Septage pumpers and haulers are generally small businesses. A typical septage pumper and hauler removes between 500 and 1,000 gallons of septage from a residential septic or holding tank once every three to five years. The typical maximum capacity of a septic tanker that is hauling septage for land application is between 2,000 and 4,000 gallons. The solids content of septage is less than five percent. Using the same reasoning as that for sewage treatment works with flows of one MGD or less, the maximum amount of septage solids that could be land applied on any given area of land on an annual basis would be small. Even if this septage contained in excess of 300 ppt TEQ dioxins on a dry matter basis, the quantity of dioxins being land applied would be insignificant.

### C. Proposal for Sewage Sludge that is Placed in a Surface Disposal Unit or Incinerated in a Sewage Sludge Incinerator

EPA is proposing to take no action to regulate current surface disposal or incineration practices for dioxins. As explained below in Sections V.C. and D., we do not predict an unreasonable risk of adverse effects to human health from cancer as a consequence of either placement in a surface disposal unit or incineration in a sewage sludge incinerator. Therefore, no additional numeric limit or operational standard or monitoring is being proposed for part 503, subparts C and E. We invite comment on proposing no action to regulate dioxins in sewage sludge that is placed in a surface disposal unit or incinerated in a sewage sludge incinerator.

### D. Estimate of Costs

The increased costs which would be imposed by this proposed regulation are the costs for initially monitoring for dioxins by all land applying treatment works greater than one MGD, annual monitoring at those facilities with dioxin levels between 30 ppt TEQ and 300 ppt TEQ, and switching to co-disposal with municipal solid waste for current land appliers whose sewage sludge contains over 300 ppt TEQ of dioxins. We assume that the cost of measuring dioxins in sewage sludge is $2000 per sample and the cost to switch to co-disposal with municipal solid waste is $189 per dry metric ton in 1998 dollars. We estimate that the annualized cost of this regulation nationwide would be approximately $18 million. Of this amount, 13 percent is for monitoring, and the balance is for switching use or disposal practices.

The permitting authority, whether Federal or State, should not accrue any significant permitting burden as a result of these proposed part 503 amendments. The part 503 standards were designed to

be self implementing and independently enforceable in the absence of a Federal permit. These proposed amendments merely add an additional numerical standard to the original part 503 rule which was promulgated in 1993.

## V. Risk Assessment Methodologies and Results

### A. Approach and Assumptions in EPA's Risk Assessments for Exposure to Doxins Resulting from Sewage Sludge Use or Disposal Practices

The four steps of the risk assessment process include hazard identification, dose-response assessment, exposure assessment, and risk characterization. We conducted risk assessments for land application of sewage sludge, surface disposal of sewage sludge, and incineration of sewage sludge in a sewage sludge incinerator. All three risk assessments used the same hazard identification and dose-response data and assumptions. However, the risk assessments examined different exposure pathways and have different risk characterizations. The following presents an overview of the approach used for these risk analyses and a general description of the assumptions common to all three risk assessments.

Today's proposal is based on assessments of the risks to human health posed by dioxins that might be in sewage sludge or sewage sludge incinerator emissions using a deterministic risk analysis. A deterministic risk analysis produces a point estimate of risk or hazard for each person based on using a single value for each parameter in the analysis. A parameter is any one of a number of inputs or variables, such as soil to plant dioxin uptake coefficients, required for the fate and transport and exposure models and equations that EPA uses to assess risk. In some cases EPA selects a single set of multiple parameters for the purpose of conducting our analyses. We do this to prevent inadvertently combining parameters in our analyses in ways that are unrealistic. For example, EPA treats

environmental setting (location) parameters such as climate, depth to groundwater, and aquifer type as a single set of parameters. We believe that, for example, allowing the climate from one location to be paired with the depth to groundwater for another location could result in a scenario that would not occur in nature.

EPA conducts both "central tendency" and "high end" deterministic risk assessments to attempt to quantify the potential cancer risk for the "average" person in the population (the central tendency risk) and the risk or hazard for individuals in small, but definable "high end" segments of the population (the high end risk). For central tendency deterministic risk analyses, we set all parameters at their central tendency values. For the sewage sludge risk assessments, the central tendency values generally are either mean (average) or 50th percentile (median) values.

We use high end deterministic risk analysis to estimate potential risks and hazards for those individuals exposed at the upper range of the distribution of exposures. EPA's Guidance For Risk Characterization (USEPA, 1995) advises that "conceptually, high end exposure means exposure above about the 90th percentile of the population distribution, but not higher than the individual in the population who has the highest exposure," and recommends that "the assessor should approach estimating high end by identifying the most sensitive variables and using high end values for a subset of these variables, leaving others at their central values." For the sewage sludge high end deterministic risk analyses, EPA used exposure pathways that we consider to represent how people may encounter the most potential exposure to dioxin; chose the $95^{th}$ percentile concentration (USEPA, 1999e) of dioxins in sewage sludge and the highest dioxin emitting incinerators; and used one other high end exposure

factor from the Agency's Exposure Factors Handbook (USEPA, 1997) to perform a conservative public health analysis.

The hazard identified for these risk assessments is cancer as a human health endpoint from the compounds assessed. We took into account the impacts on human cancer risk nationwide. We examined the cancer toxicity of 2,3,7,8-TCDD and estimated several dose- response relationships for this congener (USEPA, 1994). The toxicity of the other congeners included in the current risk assessment are expressed in relation to the cancer toxicity of 2,3,7,8-TCDD using guidance we published (USEPA, 1989) and from information published in the scientific literature (Van den Berg, et. al., 1998).

Regarding exposure pathways, our evaluation of land application considered, among other things, risks of human exposure to dioxins through (a) inhaling or ingesting soil fertilized with sewage sludge, (b) eating crops grown on this soil or animal products from livestock grazed on this soil, and (c) ingesting ground or surface water or edible aquatic organisms contaminated as a result of applying sewage sludge to land. For surface disposal of sewage sludge, we evaluated the human health risks associated with drinking ground water contaminated by dioxins or breathing air affected by volatilized dioxins. For incineration in a sewage sludge incinerator, we evaluated human exposure to dioxins directly through inhalation of gases and particles in the emissions from sewage sludge incinerators and indirectly by consumption of crops and animal products produced on agricultural lands and home gardens affected by the deposition of particles from sewage sludge incinerator emissions. We were unable to assess the ecological effects for any of the practices due to the scarcity of relevant information and evaluation methods.

As indicated above, we attempted to assess the risk both for average exposed individuals (AEI) in the population and high end exposed individuals (HEI) in the population. In these analyses for the hypothetical AEI, average values were used for all parameters to capture average risk. For the hypothetical HEI, no more than two high end values for exposure variables, such as ingestion rates and inhalation rates, were used in the assessment to estimate high end risk. These values were obtained in large part from EPA's Exposure Factors Handbook (USEPA, 1997).

You will find below descriptions of routes of exposure (called the exposure pathways) through land application, surface disposal, and incineration of sewage sludge that we assessed. We then calculated risks associated with these pathways by comparing exposures with dose-response information for the pollutants. The Technical Support Documents for this rule making (USEPA, 1999b; USEPA, 1999c; USEPA, 1999d) contain more details on the final comprehensive exposure pathway analyses, including the modeling algorithms and default parameters as well as descriptions of major uncertainties and variability.

Agency experts reviewed the risk assessments used for land application and surface disposal. EPA will submit these risk assessments to an external peer review panel in accordance with the Agency's Peer Review Guidelines during the public comment period for this proposed rule. The risk assessment used for incineration was submitted to an external peer review panel in accordance with the Agency's Peer Review Guidelines. We will consider and address peer review comments and public comments on these risk assessments.

### B. Description of Land Application Risk Assessment

We evaluated both agricultural and non-agricultural application sites associated with the land application pathways. Agricultural sites, which include rangeland and pasture, are land on which a food, feed, or fiber crop is grown. Non-agricultural sites include reclamation, public contact, and forest sites. The term "reclamation sites," defined in 40 CFR 503.11(n), refers to drastically-disturbed land that is reclaimed using sewage sludge, including strip mines and construction sites. "Public contact sites" are those that people frequent where contact is likely. Examples of public contact sites are parks, ball fields, cemeteries, plant nurseries, turf farms, and golf courses (40 CFR 503.11(l)).

### 1. Land Application Exposure Pathways

We considered 15 exposure pathways for land application of sewage sludge. Five of these pathways were not evaluated since there was insufficient data. The pathways that were not evaluated included exposure and subsequent toxicity risks from ingestion of feedstuffs grown on sewage sludge-amended soils and fed to domesticated farm animals (animals commercially produced for human consumption), exposure and subsequent toxicity risks from incidental ingestion of sewage sludge-amended soils by domesticated farm animals during pasturing and grazing, phytotoxicity effects from dioxins in sewage sludge-amended soils, and exposure of soil macro organisms and their animal predators to dioxins from sewage sludge-amended soils. We invite public comment and any information regarding the exposure pathways not evaluated in the land application risk assessment.

Exposure pathways that we fully evaluated for exposure to dioxins from land application of sewage sludge include:

- consumption of commercially grown crops by the general population
- consumption of home-grown crops by home gardeners

- incidental ingestion of sewage sludge-amended soil by children
- consumption of locally produced meat and dairy products by families living outside urban areas (taking into account both forage fed to the animals and incidental ingestion of soil by the animals)
- inhalation of dust from sewage sludge-amended soils by farm workers
- consumption of groundwater, surface water, and aquatic organisms affected by leachate and runoff from sewage sludge-amended soil
- inhalation of volatilized pollutants from sewage-sludge amended soil
- and ingestion of breast milk by infants in families living outside of urban areas

### 2. Key Assumptions for the Land Application Risk Assessment

As stated above, we evaluated pathways which represent ways in which people can be most exposed to dioxin, in combination with a concentration of 300 ppt TEQ of dioxins in sewage sludge and one other conservative exposure factor, to ensure a true high-end deterministic risk assessment. Some of the exposure factors for land application were more conservative than those used for similar incineration pathways. We did this because nationwide there are 145 known sewage treatment works with sewage sludge incinerators compared to an estimated 4,250 land application operations. We estimated the highest concentrations of dioxins for land applied sewage sludge from a statistically valid sampling of sewage sludge nationwide, while we were able to identify and directly monitor the highest dioxin emitting incinerators for this risk assessment.

For land application, we assumed that the highly exposed individual lives on the same site for 58 consecutive years. We also assumed that sewage sludge at the 95$^{th}$ percentile of concentration of

dioxins of 300 ppt TEQ as estimated in the NSSS and in a data base from a survey conducted by the Association of Metropolitan Sewerage Agencies (AMSA) (Green, et. al., 1995) is applied to the land every other year for 100 years at the rate of 10 metric tons per hectare. We note that the AMSA survey analyzed for only four of the 12 twelve coplanar PCB congeners. However, three of these congeners typically dominate the coplanar PCB TEQ values in most environmental samples and are considered adequate for generalizing dioxin-like coplanar PCB risk in support of this proposed rule. For assessing risks from individual facilities and for complying with the provisions of this proposed rule, a full 12 congener coplanar PCB analysis is required.

The risk assessment also assumes that land-applied sewage sludge is incorporated into the soil to a depth of 15 centimeters. Our assumption is that incorporation into the soil occurs either mechanically at the time of application or "naturally" over time due primarily to the effects of weather and the activity of soil organisms such as worms and grubs. The pathways which are based on direct ingestion by grazing animals or humans assume that a sludge-soil mixture is ingested. The existing part 503 regulation requires a 30-day waiting period prior grazing animals after sludge application. We are requesting comment on whether we should require mechanical incorporation of sewage sludge into the soil, whether 30 days is a sufficient waiting period to assure adequate natural incorporation into the soil, or whether the rule should require a longer waiting period.

Other key assumptions include the following:

- Crops grown on sewage sludge-amended soil are 2.5% of the lifetime diet for the general population.

- For a family living in a rural area, 10% of their beef diet, 10% of their beef liver diet, 10% of their lamb diet, and 3% of their dairy diet comes from local farms that raise animals on sewage sludge amended soils
- Produce grown on sewage sludge-amended soil are 43% to 59% of a home gardener's diet.
- Children from age 1 - 6 incidentally ingest 0.4 gram of sewage sludge-amended soil daily.
- People consume two liters of water and 39 grams of aquatic organisms daily from the same source over their lifetimes.
- The nursing period for infants is six months.

All of the assumptions for the land application risk assessment and the basis for these assumptions are described in the land application Technical Support Document (TSD) (USEPA, 1999b).

### 3. Land Application Risk Characterization

The risk assessment for the exposure pathways described above estimates high end risks. Given these conservative assumptions, the highest exposure pathways for the hypothetical highly exposed individuals for land application are rural families which consume products made from locally raised livestock that incidentally ingest sewage sludge-amended soil and nursing infants having breast milk from hypothetically highly exposed rural family mothers. The resulting high end estimate of cancer risk for any such person is 1.7 per 100,000 ($1.7 \times 10^{-5}$), which is well within the Agency's range of acceptable risk of one in one million to one in ten thousand ($1 \times 10^{-6}$ to $1 \times 10^{-4}$). However, we estimate that a very small percentage of the sewage sludge produced nationwide may exceed 300 ppt

TEQ dioxin. In order to ensure that any risks associated with land application of sewage sludge remain negligible, we propose to place a numeric limit of 300 ppt TEQ on the concentration of dioxins in sewage sludge which is land applied.

### C. Description of Surface Disposal Risk Assessment

Sewage sludge surface disposal facilities are of two types: (1) monofill and (2) surface impoundment. The monofill is a sewage sludge-only trench fill receiving dewatered sludge with a solids content greater than 20%. The surface impoundment receives a continuous inflow of sewage sludge with a low solids content of between 2% and 5%. Both of these types of surface disposal facilities were subjected to the risk assessment for dioxins. The surface impoundment clearly offered the greater potential to emit dioxins to the environment and subsequently expose an individual to these pollutants. The results of the risk assessment with estimated incremental risks to the highly exposed individual are based, therefore, on the surface impoundment.

#### 1. Surface Disposal Exposure Pathways

The only two possible exposure pathways to an HEI are volatilization of dioxins from the facility with subsequent inhalation of these pollutants and the leaching of dioxins to groundwater with subsequent consumption of this groundwater. Based on the required management practices of these facilities, there is an insignificant chance that dioxins would be released to surface waters even during extreme wet weather conditions. Food chain pathways which are critical in the land application risk assessment are not relevant.

#### 2. Key Assumptions for the Surface Disposal Risk Assessment

The HEI for exposure to surface disposal facilities is a person who resides in immediate proximity (within 150 meters) to the site. We assumed that this person spends his/her entire life at this site. We also assumed that this person inhales outdoor air from this site 16 hours per day and indoor air from within his/her residence adjacent to this site for eight hours per day. We set water consumption at two liters per day of groundwater obtained within 150 meters from the edge of this site at an assumed depth to groundwater of one meter. We assumed moderately porous soils for the surface impoundment with no synthetic liner to retain leachate (USEPA, 1999a).

### 3. Surface Disposal Risk Characterization

The maximum incremental cancer risk to the HEI did not exceed one in ten million ($1 \times 10^{-7}$) for either exposure pathway (USEPA, 1999b). Dioxins have extremely low volatility and would not be expected to offer significant exposure to the HEI through inhalation. Also, dioxins do not dissolve readily in water. Even in the absence of a liner, combined with high porosity soil and a short distance to ground waters as assumed in the risk assessment, only insignificant amounts of dioxins could ever reach the groundwater. For these reasons, we are proposing no action to regulate dioxins for sewage sludge surface disposal.

## D. Description of Incineration Risk Assessment

We used four steps to estimate risks from firing sewage sludge in sewage sludge incinerators. First, we estimated the rate at which pollutants are emitted from incinerator stacks. Next, we estimated the movement of pollutants in air near incinerators, including how much pollutant plumes overlap. We then overlaid maps of expected ground-level concentrations of pollutants and human populations.

Finally, we determined the extent and nature of resulting health risks of human exposure to emitted dioxins.

The last step was a multi-pathway risk assessment for exposure to dioxins that result from the firing of sewage sludge in a sewage sludge incinerator. The risk assessment estimated hypothetical average and high end risks to the highly exposed sub-populations of farmers and home gardeners. We evaluated the risk to the hypothetical highly-exposed individual who is exposed by both a direct route like inhalation and other routes through eating contaminated food. In addition, we conducted a probabilistic analysis of uncertainty for the home gardener and for the farmer to quantify uncertainty and estimate the range of calculated risks possible for the facilities modeled.

We considered multiple hearth units without afterburners to be the worst case technology for sewage sludge incineration and likely the highest emitters of dioxins and coplanar PCBs. To provide a high end to estimate of the risk from sewage sludge incineration, the analysis focused on the six highest emitting incinerators for dioxins/dibenzofurans and coplanar PCBs in the United States from an initial screen of 135 incinerators.

### 1. Incineration Exposure Pathways

The assessment considered, but did not evaluate, all 15 exposure pathways considered in the land application risk assessment. We evaluated those pathways expected to result in the highest risk estimates for which data were available. We selected two exposure scenarios to represent highly exposed sub-populations that reside near sewage sludge incinerators: (1) beef and dairy farmers consuming, at recreational fisher levels, fish caught near sewage sludge incinerators, and (2) home gardeners consuming as a portion of their diet home-grown produce grown near a sewage sludge

incinerator. For both scenarios, we estimated average and high end exposures for children and adults at locations where they are expected to reside. We used a geographical information system to identify land uses and terrain around facilities, to identify watershed and water body parameters to estimate fish and drinking water ingestion risks, and to provide census information about farmers and residents exposed to incinerator emissions. We estimated numbers of individuals exposed and the associated risks for six population age groups.

### 2. Key Assumptions for the Incineration Risk Assessment

Many important factors in estimating exposure vary from one facility to the next, and as a result, the highest emitting facility will not always produce the highest risk. We therefore selected the six highest emitting incinerators that also resulted in the highest potential inhalation exposures from the initial screening assessment of 135 incinerators. The variables that are important for exposure assessment and considered in the screen include, for example, distance to exposed population, activities of the exposed population, effective release height of pollutants, and meteorological conditions. We also considered emission rates, emission release characteristics, and actual populations near the facilities in the initial screening assessment.

To address high end risk, plausible ranges of values for key exposure and model variables were modeled via Monte Carlo procedures to estimate the range of possible risk values and their probability of occurring. The variables considered for the Monte Carlo modeling were identified by sensitivity analyses. The variables were exposure duration, beef and dairy consumption, beef and dairy biotransfer factors, air to plant transfer, dry sludge throughput, adult inhalation rate, and fraction of time an adult is indoors and outdoors.

The large number of exposure values used in the risk assessment are shown in Appendix B of the TSD for incineration (USEPA, 1999c). The following is a summary of a few key values:

- Adult body weight of 71.8 kilograms (kg)
- Body weight of a 3-5 year old is 17.5 kg
- Exposure duration for farmer is 17.3 years
- Exposure duration for home gardener is 12 years
- Adult inhalation rate of 13.3 cubic meters each day
- Child 3-5 years old inhalation rate is 8.3 cubic meters each day
- Child daily soil ingestion rate of 0.1 grams each day
- Adult daily soil ingestion rate of 0.05 grams each day
- Adult daily fish ingestion rate of 0.162 grams per kg. body weight per day

For the farmer exposure pathway, we evaluated the inhalation of vapor and particle-bound pollutants released from the incinerator stack(s), soil ingestion, ingestion of homegrown fruits and vegetables, ingestion of home-produced beef and dairy products, ingestion of drinking water from nearby surface water bodies, and ingestion of fish at recreational fisher levels from those water bodies. The home gardener pathway included inhalation of vapor and particle-bound pollutants, soil ingestion, ingestion of homegrown fruits and vegetables, and ingestion of drinking water from surface water bodies. For infants in both pathways, breast milk ingestion from an adult's exposure to the above pathways is included. Dermal exposure to soil and water and consumption of other animal products were not quantified since exposures from these pathways are expected to be significantly less than the pathways evaluated.

### 3. Incineration Risk Characterization

We found that average and high-end risks were higher for the farmer than for the home gardener. Estimated risks were higher for individuals closer to the facility than farther away. The most significant pathway for the farmer was ingestion of home-grown beef and dairy products and for the home gardener ingestion of home-grown produce. For infants of farmers, the breast milk ingestion pathway is often the most significant. For the six facilities, at locations where farmers and home gardeners are likely to reside, none of the estimated risk exceeded $1x10^{-6}$, including the estimated risk for infants. Based on census data, only extremely small numbers of farm families are predicted to be exposed to risk levels near the upper end of the predicted range.

Additionally, the concentration of dioxins in sewage sludge being fed into sewage sludge incinerators does not influence the amounts of dioxins being emitted from the incinerator. The key factors influencing the amount of dioxins being emitted are the combustion conditions in the incinerator, incinerator design, and the efficiency and operational conditions of any air pollution control devices used on the incinerator. The Agency's most recent publicly available Dioxin Source Inventory associated with the Draft Dioxin Reassessment (USEPA, 1998) estimated that total dioxins (chlorinated dioxins and chlorinated dibenzofurans only) being emitted from all of the Nation's sewage sludge incinerators was approximately 14.6 grams TEQ per year, a very minor fraction of the total North American dioxin inventory. These amounts are expected to be further reduced over the next several years as the requirement for all sewage sludge incinerators to comply with either 100 parts per million (ppm) total hydrocarbons (THC) or 100 ppm carbon monoxide (CO) in their emissions is implemented.

We investigated plans for any future changes for the six multiple hearth incinerators (MHI) used in the risk assessment to determine if any significant reductions in emissions of dioxin and dioxin-like compounds might be expected in the future. Three of the six incineration facilities indicated that no changes that might reduce emissions were planned in the foreseeable future. They are currently meeting the total hydrocarbon emission limitation of 100 ppm.

Two of the six incineration facilities indicated replacement of the existing multiple hearth incinerators is taking place. One of these facilities is bringing a fluidized bed incinerator (FBI) on line in the first quarter of 2000, which will operate as the primary incinerator. The currently operating MHI will be shut down and will remain as a backup incinerator, with only occasional use. Tests of FBIs has demonstrated more complete destruction of organic compounds than in MHI. The other facility expects to shut down its incineration operation completely in 2001 and start drying sewage sludge instead. Drying involves lower temperatures and no combustion of the sewage sludge, so this facility will significantly reduce or eliminate emissions of organic pollutants.

The largest and highest emitting of the incineration facilities plans to start to eliminate incineration of sewage sludge in their multiple hearth incinerators over the next four to five years. The facility is working to evaluate a new high temperature process that will convert sludge to a glass-like aggregate. The facility expects to submit a permit application within three years to build the first aggregate unit. If this initial unit is successful, they will submit another permit application to build additional units to replace the entire multiple hearth incineration facility. However, if the new aggregate process does not prove to be feasible, then this facility will continue to use the existing multiple hearth incinerators. The facility may consider building FBIs to start replacing aging MHIs.

On August 4, 1999, we promulgated amendments to the incineration subpart of the part 503 standards. 64 FR 42552. The amendments included a provision making all sewage sludge incineration requirements self-implementing. All incinerator owners/operators must now continuously monitor for either THC or CO emissions and operate their incinerators to limit either THC or CO emissions to 100 ppm or less (40 CFR 503.40(c), 503.44, 503.45(a)). We will continue to inspect the operations and records of these incinerators to assure attainment of THC or CO limits.

Based on the results of the risk assessment for dioxins in sewage sludge fired in sewage sludge incinerators and the information we have regarding actual and projected incineration of sewage sludge in sewage sludge incinerators, we are proposing no national standard for incineration of sewage sludge in sewage sludge incinerators. We seek comment on this proposal.

## VI. Other Options that EPA Considered

### A. Numeric Standards for all Use or Disposal Practices

Under this option, we would propose comprehensive risk-based regulations setting numeric standards for dioxins, as well as monitoring requirements, reporting, and record keeping provisions for all sewage sludge use or disposal practices. We are not proposing this option for surface disposal or incineration in a sewage sludge incinerator. As previously explained, the risk assessments for surface disposal and incineration did not show that the risk from placing sewage sludge on a surface disposal site or firing sewage sludge in a sewage sludge incinerator, including the highest emitting type of sewage sludge incinerator, posed an unreasonable risk to human health. We invite public comment on whether EPA should establish numeric limits for dioxins in sewage sludge for all use or disposal methods.

### B. Require all Sewage Sludge to be Landfilled or Surface Impounded

Under this option, we would propose a rule under part 503 that would require all sewage sludge to be placed in a landfill or surface impoundment. The rule would be based on total containment of dioxins in sewage sludge and would virtually eliminate all exposure to dioxins from sewage sludge. The risk assessments performed did not indicate unreasonable risk from exposure to land applied sewage sludge with dioxins content of 300 ppt TEQ or less or from exposure to emissions from sewage sludge incinerators with any level of dioxins in the incinerated sewage sludge. Therefore, we are not proposing this option.

### C. No Further Regulation of Sewage Sludge for any Use or Disposal Practice

We considered this option for land application, as well as for surface disposal and incineration. As discussed above, the risk assessment shows that sewage sludge with 300 ppt TEQ dioxins that is land-applied poses a human cancer risk in excess of one in one hundred thousand ($1 \times 10^{-5}$) cancer risk only for highly exposed subpopulations using conservative assumptions. The estimated risk of $1.7 \times 10^{-5}$ is approximately one-fifth of the background risk posed by dioxins from all other sources (USEPA, 1994). However, data from the NSSS (USEPA, 1990) show that some treatment works produced sewage sludge containing dioxin/dibenzofurans (not including coplanar PCBs) as high as 1700 ppt TEQ. Although we have not done a detailed risk assessment of the potential impacts of this highest concentration, we believe that the incremental cancer risk would likely be on the order of one in ten thousand

($1 \times 10^{-4}$) for highly exposed subpopulations using conservative assumptions. This level of risk would be within the Agency's acceptable range of $1 \times 10^{-6}$ to $1 \times 10^{-4}$. Nevertheless, we believe the better course of action is to propose a numeric limit for dioxins in sewage sludge that is applied to the land at a

level which limits the incremental risk to approximately $1x10^{-5}$ to $2x10^{-5}$. This approach limits incremental risks for dioxins to levels well below background, because of concern with multiple sources and possible cumulative exposures. The Agency recognizes that its use of "highly exposed individuals" and other conservative assumptions also builds in some margin of safety. Therefore, we request comment on taking no action with respect to regulating dioxins for land application of sewage sludge.

## VII. Request for Public Comments

While we are requesting comments on all aspects of this proposed rule, we hope that public comments will also focus specifically on the following aspects of this proposal:

(1) Establishing of a cap of 300 ppt TEQ dioxins for land applied sewage sludge that will protect a highly exposed individual from an incremental cancer risk of not greater than $1.7x10^{-5}$ (IV.B.1).

(2) Using EPA Analytical Method 1613B for the chlorinated dioxin and dibenzofuran congeners and EPA Analytical Method 1668 or 1668A for co-planar PCB congeners (IV.B.3).

(3) Requiring two consecutive years of monitoring results under 30 ppt TEQ before allowing a reduced monitoring schedule (IV.B.4).

(4) Our assumption that the level of dioxins in sewage sludge is relatively constant over time and may possibly be decreasing (IV.B.4).

(5) Whether we have clarified existing monitoring requirements by separating §503.16(a) into two paragraphs or if our proposed change unintentionally changes the substance of the frequency of monitoring provisions currently in §503.16(a)(1) (IV.B.4).

(6) Requesting information on the dioxin content, annual application rates, numbers and sizes of sites, and applications per site for sewage sludge from treatment works with a flow rate of one MGD or less

and whether to exempt small treatment works from both the initial monitoring requirements and the dioxin limit for land application.

(7) Our proposed designation of small treatment works as one with a flow rate of one MGD or less, and our proposed designation of other small sludge preparers that are not treatment works as those preparing sewage sludge for land application in an amount of 290 dry metric tons or less annually (IV.B.5)

(8) Requesting information on exposure pathways not evaluated, including direct risks to livestock, soil organisms, wildlife, and plants, resulting from dioxins in sewage sludge that is land applied or incinerated (V.B.1, V.D.1.).

(9) Proposing no action in regulating dioxins in sewage sludge that is placed in a surface disposal unit or incinerated in a sewage sludge incinerator (V.C.3, V.D.3).

(10) Whether EPA should establish numeric limits for dioxins in sewage sludge for all use or disposal methods (VI.A).

(11) Proposing no action for dioxins in sewage sludge that is land-applied (VI.C)

(12) Whether there are any privately-owned treatment works with flows greater than one MGD that also have revenues less than $6 million. If such facilities are operating, we request information on flow, revenues, and sludge disposal methods (VIII.B).

(13) Data on the cost to switch from land application to alternative use or disposal practices (compared to our assumption of $189 per dry metric ton to switch to co-disposal with municipal solid waste) (VIII.B).

(14) Potential impacts of the proposed rule on small entities and on issue related to such impacts (VIII.B).

(15) The use of the proposed alternative definition of small entity–both for this proposed rule and for subsequent rulemakings (VIII.B.)

(16) Consensus methods that are suitable for compliance monitoring for determining concentrations of dioxins, furans, and coplanar PCBs in sewage sludge (VIII.H).

## VIII. Regulatory Assessment Requirements

### A. Executive Order 12866, Regulatory Planning and Review

Under Executive Order 12866, [58 Federal Register 51,735 (October 4, 1993)] the Agency must determine whether the regulatory action is "significant" and therefore subject to OMB review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal government or communities;

(2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that this rule is not a "significant regulatory action" under the terms of Executive Order 12866 and is therefore not subject to OMB review.

**B. Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq.**

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

Today's proposal affects two categories of entities: (1) publicly-owned treatment works (POTWs) owned by local governmental jurisdictions, and (2) privately-owned treatment works and sludge-only preparers, which are businesses. For this proposal, EPA first assessed the effects on small entities using the small entity definition for each category as defined in the RFA. EPA also assessed the effects of the proposal using the alternative definition for each category of small entity that EPA is proposing to establish for this rule. (See the discussion under "Use of Alternative Definition" later in this section.)

For purposes of assessing the impact of today's proposal on small entities, small entities are defined as (1) a small business that meets RFA default definitions based on SBA size standards found in 13 CFR 121.201 (i.e., small refuse systems that have less than $6 million in annual revenues); (2) a small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit

enterprise which is independently owned and operated and is not dominant in its field.

To evaluate the economic impact on small governmental jurisdictions subject to today's rule, EPA looked at the effect on municipalities owning a POTW that services a population of 50,000 or fewer with complete jurisdiction over all indirect discharges to and discharges from a treatment works. EPA considers this an appropriate surrogate for small governmental jurisdictions. (EPA recognizes that, to the extent a governmental jurisdiction may own more than one POTW serving a population of 50,000, this evaluation may overstate the number of small governmental jurisdictions.)

Based upon average domestic sewage loadings, a POTW serving a population of 50,000 or fewer would correspond to one processing approximately five million gallons per day (five MGD) of wastewater. EPA's data, however, do not permit it to accurately estimate the number of POTWs in a one to five MGD range because EPA collected information for the flow range of one MGD to ten MGD. Therefore, in order to determine the impact on small governmental jurisdictions, EPA first looked at the economic impact of today's proposal on those POTWs with one to ten MGD flows who land apply their sewage sludge because the proposed dioxin limit would apply only to those POTWs that land apply their sewage sludge. EPA estimates that there are approximately 890 POTWs in the one to ten MGD flow range who land applied their sewage sludge. EPA estimated costs for these facilities to comply with the proposed monitoring requirements, as described in Section IV.D. EPA estimates annual monitoring costs of $2,000 to test for the parameters included in today's proposal. The frequency of this monitoring varies, depending on the outcome of the test, as explained in Section IV.B.4. EPA also estimated incremental disposal costs for between 40 and 50 facilities in the one to

ten MGD flow range with sewage sludge that might exceed the proposed 300 ppt TEQ numeric limit for dioxins in sewage sludge. EPA estimates that the costs of the proposal would not exceed $6 million for the group of POTWs in the one to ten MGD flow range.

For purposes of evaluating the economic impact of this rule on small governmental jurisdictions, EPA compared costs with average annual revenues for small governmental jurisdictions obtained from the 1992 Census of Governments. The Census data are reported at a level of detail that allow EPA to focus on the small governmental jurisdictions, as defined in the RFA. The data further allow EPA to limit the revenue information to populations between 10,000 and 50,000, which correspond to the small POTWs covered by the proposed rule. (POTWs with flows at or below one MGD are exempt from this rule.) The revenues for the governmental jurisdictions in the 10,000 to 50,000 population group are approximately $57 billion. The costs of the proposed rule represent less than 0.01 percent of the entities' revenues. In other words, when EPA divided the total compliance costs for the group of POTWs (i.e., costs of $6 million) by the revenues for the group of small governmental jurisdictions (i.e., revenues of $57 billion), those costs are only one, one-hundredth of the revenues. EPA concludes that the rule will not have a significant impact on a substantial number of small governmental jurisdictions owning these POTWs.

For privately-owned treatment works, the RFA definition of small entity is a small business as defined in U.S. Small Business Administration (SBA) regulations at 13 CFR 121.201. Those regulations define small refuse systems (Standard Industrial Classification 4953) as having less than $6 million in annual revenues. In the Regulatory Impact Analysis for the previous Part 503 regulations (EPA 821-R-93-006, March 1993), EPA concluded that the universe of privately-owned treatment

works is limited to facilities with wastewater flows below one MGD. Today's proposed regulation excludes treatment works with flows at or below one MGD; thus, EPA concludes that the proposed rule imposes no requirements on small, privately-owned treatment works. Although EPA estimates that a privately-owned treatment works with annual revenues near $6 million (if one exists) corresponds to flows much greater than one MGD, EPA has not identified any such treatment works. Theoretically, any privately-owned treatment works with flows greater than one MGD and also having revenues less than $6 million would be small entities, as defined by the RFA. EPA solicits comment on whether such treatment works are operating, and if so, requests information on flow, revenues, and sludge disposal methods.

For sludge-only preparers, under the RFA definition cited above, a small entity is a preparer with annual revenues of less than $6 million. EPA data suggest that there are substantially fewer than 100 sludge-only preparers that are small entities. EPA first considered the potential impacts to a subset of small preparers – those with annual revenues less than $80,000, which corresponds to production of approximately 290 dry metric tons of sewage sludge. EPA equates a production level of 290 dry metric tons of sewage sludge to a wastewater flow of one MGD. Today's proposed rule excludes this subset of very small sludge-only preparers (see Section IV.B.5.). Thus, this analysis suggests for sludge-only preparers with annual revenues less than $80,000, today's proposed rule imposes no requirements. For the remaining sludge-only preparers that are also small businesses (by RFA definition), i.e., those with annual revenues between $80,000 and $6 million, EPA estimated the potential impacts as additional monitoring costs (see Section IV.D.). For the small preparers with revenues between $80,000 and $6 million, the estimated impacts will range from 0.03 to 2.5 percent of

revenues. Thus, EPA estimates that there is not a significant economic impact on a substantial number of small sludge-only preparers.

After considering the economic impacts of today's proposed rule on small entities, I certify that this action will not have a significant economic impacts on a substantial number of small entities. EPA nonetheless has tried to reduce the impacts of this rule on small entities. For example, the proposed rule imposes no requirements on treatment works (public or private) with flows less than or equal to one MGD. This regulatory exclusion markedly limits the number of treatment works with monitoring requirements. These smallest POTWs and privately-owned treatment works will face no changes in their sludge disposal operations. We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

*Use of Alternative Definition*

As noted, EPA is certifying that the proposed rule will not have a significant economic impact on a substantial number of small entities, using the RFA definitions for small entities. However, the RFA authorizes an agency to use alternative definitions for each category of small entity, "which are appropriate to the activities of the agency" after proposing the alternative definition(s) in the *Federal Register* and taking comment. 5 U.S.C. §§ 601(3)-(5). In addition, to establish an alternative definition for small business, agencies must consult with SBA's Chief Counsel for Advocacy.

In today's rule, EPA is proposing to define "small entity" for purposes of its regulatory flexibility assessments under the RFA as follows: EPA is proposing to define "small governmental jurisdiction" as any municipality or special district operating a POTW with a capacity of one MGD or less. Generally flows in this size range correspond to service populations of 10,000 or less. EPA also is

proposing to define "small business" as a privately-owned treatment works with a capacity of one MGD or less and sludge-only preparers with finished product amounts of 290 dry metric tons or less of sewage sludge. EPA will initiate consultation with the SBA on the alternative definition for "small business" shortly.

EPA is proposing these alternative definitions for the purpose of consistency within the sewage sludge use or disposal program. When EPA published the Standards for the Use and Disposal of Sewage Sludge in 1993, the Agency used the one MGD definition for its regulatory flexibility assessment. At that time (and in the 1990 Notice of Data Availability, 55 FR 47210 (Nov. 9, 1990) (USEPA, 1990)), EPA noted the well-accepted and frequent use of this definition for small POTWs. The existing part 503 land application rule differentiates between treatment works with flow rates of one MGD or less and larger treatment works. Treatment works with flow rates of one MGD or less are required to monitor less frequently and they are excluded from reporting requirements.

In addition to proposing to establish these alternative definitions for this rule, EPA also is proposing to establish and use these alternative definitions of "small entity" for purposes of its regulatory flexibility assessments under the RFA for any subsequent rulemakings pursuant to section 405 of the Clean Water Act, 33 U.S.C. § 1345 and amendments to 40 CFR 503.

The Agency is interested in receiving comments on the use of this alternative definition of small entity – both for this proposed rule and for subsequent rulemakings.

If EPA had used the alternative definitions in its RFA assessment of the impact of today's proposed rule on small entities that would be subject to the requirements of the rule, the analysis would have supported the same conclusions; i.e., EPA would certify that there is no significant economic

impact on a substantial number of small entities. The proposed rule would not impose any requirements on POTWs and privately-owned treatment works with wastewater flows at or below one MGD. Consequently, the proposed rule would not have any economic impact on small governmental jurisdictions and small businesses that are treatment works under the alternative definitions. Similarly, for sludge-only preparers, with a small entity definition based on 290 dry metric tons of sewage sludge, the proposed rule would not have any economic impact on small businesses that are sludge preparers.

### C. Paperwork Reduction Act

The Office of Management and Budget (OMB) approved the information collection requirements for existing 40 CFR part 503 under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* (PRA) and assigned OMB Control No. 2040-0004.

The information collection requirements in this proposed rule have been submitted for approval to OMB under the PRA. An Information Collection Request (ICR) document has been prepared by EPA (ICR No. 0229.14) and a copy may be obtained from Sandy Farmer by mail at OP Collection Strategies Division; U.S. Environmental Protection Agency (2822); 401 M St., S.W.; Washington, DC 20460, by email at farmer.sandy@epamail.epa.gov, or by calling (202) 260-2740. For technical information contact Arleen Plunkett by calling (202) 260-3418. A copy may also be downloaded off the internet at http://www.epa.gov/icr.

This proposed rule will require certain sewage treatment plants which produce sewage sludge that is applied to the land and other preparers of sewage sludge for application to the land to monitor their sewage sludge for dioxins and keep records of the analytical results. Entities which monitor for

dioxin in their sewage sludge will be required to submit these records to the permitting authority. This information is needed by the permitting authority to ensure compliance with the proposed numerical standard for dioxins, thereby assuring that the acceptable incremental risk to the highly exposed individual from exposure to dioxins from land application of sewage sludge is not exceeded. The responses to the collection of information will be mandatory pursuant to section 405(d) of the CWA, 33 U.S.C. 1345(d).

The Agency has estimated the total respondent burden hours and costs for these requirements of the proposed rule. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

The Agency estimates that each respondent, when required to monitor for dioxins, will expend a total of one hour to sample their sewage sludge, submit this sample to a laboratory for dioxins analysis, receive the analytical result from the laboratory, record the result, and for certain size entities, report this result to the permitting authority. EPA estimates that in the first year that this rule is in effect, 1154 facilities will perform dioxin monitoring. The total national burden is, therefore, estimated to be 1154 hours. During the second year that this rule is in effect, 1096 facilities will be performing

monitoring for a total burden of 1096 hours. From the third year on, the Agency estimates that annually 754 facilities will be monitoring for dioxins for a total burden of 754 hours per year.

Analytical costs per sample are estimated to be $2,000. Therefore in year one, total analytical costs to the 1154 respondents are estimated to be $2,308,000. Total analytical costs for the 1096 respondents in year two are estimated to be $2,192,000. Total analytical costs for the 754 respondents in year three and beyond are estimated to be $1,508,000 annually.

For the permitting authorities, whether they are the EPA Regional Offices or the three States that have received authority to administer the part 503 regulatory program (i.e., Utah, Oklahoma, and Texas), the Agency estimates that each will be required to spend one hour to review the analytical information submitted by the respondents. Therefore, the three States identified above and the 10 EPA Regions will expend a total of 13 hours annually due to these dioxin monitoring, recordkeeping, and reporting requirements.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 15.

### D. Unfunded Mandate Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), P.L. 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, and tribal governments, in the aggregate or to

the private sector of $100 million or more in any one year. Before EPA can promulgate a rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with other applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the Administrator publishes with the final rule an explanation of why that alternative was not adopted.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA, a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA has determined that today's proposed rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. The highest estimated total costs in any one year (1998 dollars) of today's proposed rule are $18 million. Thus, today's proposed rule is not subject to the requirements of sections 202 and 205 of the UMRA.

As indicated in the Regulatory Flexibility Act discussion (see Section VIII. B.), we have determined that this rule will not have a significant impact on a substantial number of small governments. Additionally, this rule will not uniquely impact small governments because it applies to both large and

small entities. Today's proposed rule exempts wastewater treatment works with flows of less than one MGD from the provisions of this proposed rule including monitoring requirements. This exemption for these low flow wastewater treatment works, therefore, will not create any costs for the small size municipalities or small private sector firms that own and operate these facilities. Thus, today's proposed rule is not subject to the requirements of section 203 of UMRA.

### E. Executive Order 13132, Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

Under section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

Section 4 of the Executive Order contains additional requirements for rules that preempt State or local law, even if those rules do not have federalism implications (i.e., the rules will not have

substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government). Those requirements include providing all affected State and local officials notice and an opportunity for appropriate participation in the development of the regulation. If the preemption is not based on express or implied statutory authority, EPA also must consult, to the extent practicable, with appropriate State and local officials regarding the conflict between State law and Federally protected interests within the agency's area of regulatory responsibility.

This proposed rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This proposal would add a regulated pollutant to one part of the existing regulatory program, however it would not change the existing relationship between federal, State, and local officials. Thus, the requirements of section 6 of the Executive Order do not apply to this proposed rule.

This proposed rule will preempt State and or local law that is less stringent or inconsistent with these provisions, consistent with CWA section 510, 33 U.S.C. 1370. By publishing and inviting comment on this proposed rule, EPA hereby is providing State and local officials notice and an opportunity for appropriate participation. Thus, EPA has complied with the requirements of section 4 of the Executive Order.

### F. Executive Order 13084, Consultation and Coordination with Indian Tribal Governments

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal governments provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's proposed rule does not significantly or uniquely affect the community of Indian tribal governments nor does it impose substantial direct compliance costs on them. As indicated in the Regulatory Flexibility Act discussion (see Section VIII. B.), we have determined that this rule will not have a significant impact on a substantial number of small governments. The impact on Tribal governments would similar to that on small governments. We, therefore, don't expect this rule to have a significant impact on tribal governments. Neither do we expect this rule will impose substantial direct compliance costs on them. Additionally, this rule will not uniquely impact the communities of Indian tribal governments because it applies to all entities which land apply sewage sludge. Today's proposed rule exempts small wastewater treatment works with flows of less than one MGD from the provisions of

this proposed rule including monitoring requirements. This exemption for these low flow wastewater treatment works, therefore, will not create any costs for the small size tribal governments that own and operate these facilities. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

### G. Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks

Executive Order 13045 (62 *FR* 19885, April 23, 1997) applies to any rule that: (1) is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This proposed rule is not subject to the Executive Order because it is not "economically significant" as defined in EO 12866, and because the Agency does not have reason to believe the environmental health and safety risks addressed by this action present a disproportionate risk to children. Nevertheless, under EPA policy (EPA Policy on Evaluating Health Risks to Children), the risk assessment for this rule has addressed potential risk to breast-feeding infants and toddlers and the effects of exposure to dioxins. Two pathways of exposure are most important in addressing the risk potential for children. In the pathway which assumes incidental ingestion, we assumed that the toddler from ages one to six eats 0.4 gram of soil mixed with sewage sludge every day for five years. In the

breast-feeding infant pathway**,** the hypothetical highly exposed individual is the nursing infant (the nursing period is six months) of the rural family mother who eats, on a yearly basis, 10% of her beef, 10% of her beef liver, 10% of her lamb and 3% of her dairy products from animals raised on the farm and fed forage grown on sewage sludge-amended soils. Moreover, the animals are exposed through ingestion of sewage sludge and soils through grazing on pasture. The breast-feeding infant pathway was one of the pathways used for setting the proposed numeric limit.

Our assessment of these pathways does not reveal a disproportionate environmental health or safety risks to children. Incremental dioxins exposure and subsequent cancer risks from sewage sludge use or disposal practices are within the risks that would normally be expected and within EPA's range of acceptable risk.

The public is invited to submit or identify peer-reviewed studies and data, of which the Agency may not be aware, that assessed results of early life exposure to dioxins.

### H. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Pub. L. 104-113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures and business practices) that are developed or adopted by voluntary consensus standard bodies. The NTTAA directs EPA to provide Congress, through the Office of Management and Budget (OMB), explanations when the Agency decides not to use available and applicable voluntary consensus standards. This proposed rule involves technical

standards. Therefore, the Agency conducted a search to identify potentially applicable voluntary consensus standards. However, we identified no consensus methods for determination of dioxins, furans or PCBs in solid matrices such as sewage sludge. Therefore, EPA proposes to use Method 1613B and Method 1668. EPA welcomes comments on this aspect of the proposed rulemaking and, specifically, invites the public to identify potentially applicable voluntary consensus standards for determination of dioxins in sewage sludge and to explain why such standards should be used in this regulation.

## IX. List of References

Green, et. al. 1995. Comments on Estimating Exposure to Dioxin-Like Compounds: Review Draft and Addendum.

US Conference of Mayors 1999. The United States Conference of Mayors/ Urban Water Council Biosolids Land Application- The Dioxin Situation

USEPA 1989. Interim Procedures for Estimating Risks Associated with Exposure to Mixtures of Chlorinated Dibenzo-p- dioxins and -dibenzofurans (CDDs and CDFs) and 1989 Update. Washington, D.C. Risk Assessment Forum. EPA/625/3-89.016.

USEPA 1990. National Sewage Sludge Survey; Availability of Information and Data, and Anticipated Impacts on Proposed Regulations; Proposed Rule. Federal Register 55 (218): 47210-47283.

USEPA 1994. Health Assessment for 2,3,7,8-TCDD and Related Compounds. External Review Draft. EPA/600/BP-92/001a-c, and, Estimating Exposure to Dioxin-Like Compounds. Volume I. Executive Summary. Volume II. Properties, Sources, Occurrence, and Background Exposures. Volume III. Site-Specific Assessment Procedures. External Review Draft. EPA/600/6-88/005Ca-c. National Center for Environmental Assessment. Washington, D.C.

USEPA 1995. Policy for Risk Characterization. Memorandum of Carol M. Browner, Administrator, March 21, 1995, Washington, DC.

USEPA 1996. Technical Support Document for the Round Two Sewage Sludge Pollutants. Office of Science and Technology. Washington, D.C. EPA-822-R-96-003

USEPA 1997. Exposure Factors Handbook. National Center for Environmental Assessment. Washington, D.C. EPA/600/P-95/002F(a-c).

USEPA 1998. The Inventory of Sources of Dioxin in the United States. National Center for Environmental Assessment. External Review Draft. Washington, D.C. EPA/600/P-98/002Aa.

USEPA 1999a. Incremental Costs Associated with Regulating Dioxins and PCBs in Biosolids. Office of Science and Technology. Washington, D.C.

USEPA 1999b. Risk Analysis for the Round Two Biosolids Pollutants. Office of Science and Technology. Washington, D.C.

USEPA 1999c. Sewage Sludge Incinerators' Dioxin-Like Compound Risk Analysis- Draft Technical Documentation. Office of Air Quality Planning and Standards. Research Triangle Park, N.C.

USEPA 1999d. Sewage Sludge Incinerators' Dioxin-Like Compound Risk Analysis- Draft Addendum with PCB Emissions. Office of Air Quality Planning and Standards. Research Triangle Park, N.C.

USEPA 1999e. Pollutant Concentration Percentile Estimates to Support Phase II Regulations for Biosolids Use or Disposal. Office of Science and Technology. Washington, D.C.

Van den Berg M, et. al. 1998. Toxic Equivalent Factors (TEFs) for PCBs, PCDDs, and PCDFs for Humans and Wildlife. Environ. Health Perspect. 106, 775-792.

**List of Subjects in *40 CFR Part 503***

Environmental protection, Frequency of monitoring, Incineration, Intergovernmental relations, Land application, Management practices, Pathogens, Pollutants, Reporting and record keeping requirements, Surface Disposal, Vector attraction reduction.

Dated:

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**Carol M. Browner,**

***Administrator***

For the reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is proposed to be amended as follows:

## Part 503--STANDARDS FOR THE USE OR DISPOSAL OF SEWAGE SLUDGE

1. The authority citation for part 503 continues to read as follows:

**Authority:** Sections 405(d) and (e) of the Clean Water Act, as amended by Pub. L. 95-217, Sec 54(d), 91 Stat. 1591 (33 U.S.C. 1345(d) and (e)); and Pub. L. 100-4 Title IV, Sec. 406(a), (b), 101 Stat., 71, 72 ( 33 U.S.C. 1251 et seq,).

§ 503.8 [Amended]

2. Add new paragraph (b)(8) to § 503.8 as follows:

**§ 503.8 Sampling and analysis.**

* * * * *

(b) * * *

(8) *Dioxins*. EPA Method No. 1613B for the seven dioxin and ten dibenzofuran congeners. EPA Method No.1668 for the 12 coplanar polychlorinated biphenyl congeners. You can purchase a copy of EPA Method No. 1613B from the National Technical Information Service (NTIS) by requesting NTIS publication number NTIS#: PB93-236024 at 1-800-553-NTIS (or online at http://www.ntis.gov/). You can also obtain this document through the Educational Resources Information Center by requesting ERIC publication number W-105 at 1-800-443-ERIC (or online at http://www.accesseric.org/). EPA Method Number 1668 (EPA No.821/C-97-005821/C-97-005) is available on the Office of Water Methods and

Guidance Diskette #2. You can request a copy from the EPA Office of Water Resource Center at (202) 260-7786 or by sending an e-mail to: center.water-resource@epa.gov.

§ 503.9 [Amended]

3. Redesignate paragraphs (f) through (bb) as (g) through (cc) in and add a new paragraph (f) as follows:

§ 503.9 General definitions.

* * * * *

(f) *Dioxins* means all of the seven 2,3,7,8 chlorinated dibenzo-p-dioxin congeners, ten 2,3,7,8 chlorinated dibenzofuran congeners, and 12 coplanar polychlorinated biphenyl congeners as follows:

| CAS No. | Congener |
|---|---|
| 1746-01-6 | 2,3,7,8-Tetrachlorodibenzo-p-dioxin |
| 40321-76-4 | 1,2,3,7,8-Pentachlorodibenzo-p-dioxin |
| 39227-28-6 | 1,2,3,4,7,8-Hexachlorodibenzo-p-dioxin |
| 57653-85-7 | 1,2,3,6,7,8-Hexachlorodibenzo-p-dioxin |
| 19408-74-3 | 1,2,3,7,8,9-Hexachlorodibenzo-p-dioxin |
| 35822-46-9 | 1,2,3,4,6,7,8-Heptachlorodibenzo-p-dioxin |
| 3268-87-9 | 1,2,3,4,6,7,8,9-Octachlorodibenzo-p-dioxin |
| 51207-31-9 | 2,3,7,8-Tetrachlorodibenzofuran |

| CAS No. | Congener |
|---|---|
| 57117-41-6 | 1,2,3,7,8-Pentachlorodibenzofuran |
| 57117-31-4 | 2,3,4,7,8-Pentachlorodibenzofuran |
| 70648-26-9 | 1,2,3,4,7,8-Hexachlorodibenzofuran |
| 57117-44-9 | 1,2,3,6,7,8-Hexachlorodibenzofuran |
| 72918–21-9 | 1,2,3,7,8,9-Hexachlorodibenzofuran |
| 60851-34-5 | 2,3,4,6,7,8-Hexachlorodibenzofuran |
| 67562-39-4 | 1,2,3,4,6,7,8-Heptachlorodibenzofuran |
| 55673-89-7 | 1,2,3,4,7,8,9-Heptachlorodibenzofuran |
| 39001-02-0 | 1,2,3,4,6,7,8,9-Octachlorodibenzofuran |
| 32598-13-3 | 3,3',4,4'-Tetrachlorobiphenyl |
| 70362-50-4 | 3,4,4',5- Tetrachlorobiphenyl |
| 57465-28-8 | 3,3',4,4',5-Pentachlorobiphenyl |
| 32598-14-4 | 2,3,3',4,4'-Pentachlorobiphenyl |
| 31508-00-6 | 2,3',4,4',5-Pentachlorobiphenyl |
| 65510-44-3 | 2',3,4,4',5-Pentachlorobiphenyl |
| 74472-37-0 | 2,3,4,4',5- Pentachlorobiphenyl |
| 32774-16-6 | 3,3',4,4',5,5'-Hexachlorobiphenyl |
| 38380-08-4 | 2,3,3',4,4',5-Hexachlorobiphenyl |
| 69782-90-7 | 2,3,3',4,4',5'-Hexachlorobiphenyl |
| 52663-72-6 | 2,3',4,4',5,5'-Hexachlorobiphenyl |
| 39635-31-9 | 2,3,3',4,4',5,5'-Heptachlorobiphenyl |

* * * * *

§ 503.10 [Amended]

4. Amend § 503.10 by redesignating paragraph (a) as (a)(1) and adding a title to paragraph (a) before (a) (1); and adding paragraph (a)(2) as follows:

**§ 503.10 Applicability.**

(a) *General applicability of Subpart B - Land Application.*

(1) * * *

(2) The pollutant limits in § 503.13(a)(1), (a)(2)(ii), (a)(3), and (a)(4)(i) do not apply to sewage sludge prepared by, and the monitoring requirements in § 503.16(a)(3) do not apply to:

(i) A treatment works that treats domestic sewage with a flow rate equal to or less than one million gallons per day or;

(ii) A person who prepares sewage sludge or who derives a material from sewage sludge in an amount equal to or less than 290 dry metric tons per year.

* * * * *

§ 503.13 [Amended]

5. Amend § 503.13 by adding a sentence after the header to paragraph (a) and adding an entry for "Dioxins" in alphabetical order in paragraph (b)(1) and adding an entry for "Dioxins" in alphabetical order in paragraph (b)(3) as follows:

**§ 503.13 Pollutant limits**.

(a) Sewage sludge. Except as provided in § 503.10(a)(2), the following pollutant limits apply to sewage sludge that is applied to the land.

* * *

(b) * * *

(1) * * *

Table 1 of § 503.13 - Ceiling Concentrations

| Pollutant | Ceiling concentration (milligrams per kilogram)[1] |
|---|---|
| * * * * *<br>Dioxins (defined in §503.9(f))<br>* * * * * | 0.0003 TEQ |

[1] Dry weight basis

* * * * *

(3) * * *

Table 3 of § 503.13 - Pollutant Concentrations

| Pollutant | Monthly average concentration (milligrams per kilogram)[1] |
|---|---|
| * * * * *<br>Dioxins (defined in §503.9(f))<br>* * * * * | 0.0003 TEQ |

[1] Dry weight basis

* * * * *

§ 503.16 [Amended]

6. Revise (a) of § 503.16 as follows:

**§ 503.16 Frequency of Monitoring.**

(a) *Sewage sludge*. You must monitor for pollutants in sewage sludge, pathogen density and vector attraction reduction according to the following schedule:

(1) For all pollutants except dioxins listed in § 503.13(b)(1) (Table1) and (b)(3) (Table 3) and all pollutants listed in § 503.13(b)(2) (Table 2) and (b)(4) (Table 4), you must monitor as provided in Table 1 of this section.

(2) For pathogen density requirements in § 503.32(b)(2) through (b)(4) and the vector attraction reduction requirements in § 503.33(b)(1) through (b)(8), you must monitor as provided in Table 1 of this section.

Table 1 of § 503.16

| Amount of sewage sludge[1] (metric tons per 365 day period) | Frequency |
|---|---|
| Greater than zero but less than 290 | Once per year |
| Equal to or greater than 290 but less than 1,500 | Once per quarter (four times per year) |

| | |
|---|---|
| Equal to or greater than 1,500 but less than 15,000 | Once per 60 days (six times per year) |
| Equal to or greater than 15,000 | Once per month (12 times per year) |

[1] Either the amount of bulk sewage sludge applied to the land (dry weight basis), or the amount of sewage sludge or material derived from sewage sludge sold or given away in a bag or other container prepared by a person who prepares sewage sludge for application to the land (dry weight basis).

(3) Except as provided in § 503.10(a)(2), for dioxins listed in § 503.13(b)(1) and (3), you must monitor your sewage sludge annually, as of [ one year after effective date of final rule].

(i) If the level of dioxins in your sewage sludge is above 30 ppt TEQ but below 300 ppt TEQ, then you must monitor for dioxins annually.

(ii) If the level of dioxins in your sewage sludge is at or below 30 ppt TEQ for any two consecutive years, then you may reduce the frequency of monitoring to once every five years.

(iii) If you have reduced the frequency of monitoring under paragraph (a)(3)(ii) of this section and the level of dioxins in your sewage sludge exceeds 30 ppt TEQ, you must resume monitoring your sewage sludge annually.

(4) After the sewage sludge has been monitored for two years at the frequency in Table 1 of § 503.16, the permitting authority may reduce the frequency of monitoring for the pollutant concentrations and for the pathogen density requirements in §503.32(a)(5)(ii) and(a)(5)(iii).

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